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Stephen Daniel Hoath

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BARNES & THORNBURG LLP

P.O. BOX 2786

CHICAGO, IL 60690-2786

EXAMINER

VARGAS, DIXOMARA

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/583,197	Applicant(s) HOATH, STEPHEN DANIEL	
	Examiner Dixomara Vargas	Art Unit 2859	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 40-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-44, 46-49, 51, 53-57, 60, 63 and 64 is/are rejected.
- 7) ☒ Claim(s) 45, 50, 52, 58, 59, 61 and 62 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 40-44, 46-49, 51, 53-57, 60, 63 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Davey (US 6,626,027 B1).

With respect to claim 40, Davey discloses a method of testing integrity of a barrier by transferring material from one side of the barrier through a continuous path directly into a NMR analysis system and using the NMR analysis system to determine from the transferred material if there has been any leakage through the barrier (Abstract; Columns 4 and 5, lines 35-67 and 1-6 respectively).

3. With respect to claim 41, Davey discloses a method of testing integrity of a barrier by transferring material from one side of the barrier for accumulation within a NMR analysis system and using the NMR analysis system to determine from the accumulated material if there has been any leakage through the barrier (Abstract; Columns 4 and 5, lines 35-67 and 1-6 respectively).

4. With respect to claim 42, Davey discloses a method of testing integrity of a filled end product container, that is filled with the end product material, by using a NMR analysis system to determine whether end product material has leaked from the filled end product container and

Art Unit: 2859

using this determination to validate the filled end product container (Abstract; Columns 4 and 5, lines 35-67 and 1-6 respectively).

5. With respect to claim 43, Davey implicitly states the testing method with the step of performing the method without using a helium tracer added to the material since Davey discloses the tracer used could be any noble gas with a stable isotope but prefers He-3 for example (Column 3, lines 16-44).

6. With respect to claim 44, Davey discloses the step in which a pumping system is used to transfer materials into the NMR analysis system (Figure 1, #26).

7. With respect to claim 46, Davey discloses the step where a hood chamber at least partially covers (#14) and is sealed to the barrier or container surface (#20) so as to allow material from this section of the barrier or container surface to be collected for transfer into the NMR analysis system (Figure 1; Columns 4 and 5, lines 35-67 and 1-6 respectively).

8. With respect to claim 47, Davey discloses the step where the container comprises any of: electrical equipment charged with a fluid, and an inhaler charged with end product filling materials including propellant fluid, and the testing comprises testing for leakage of this fluid from the container (Figure 1, #16; Abstract; Columns 4 and 5, lines 35-67 and 1-6 respectively).

9. With respect to claim 48, Davey discloses the step of accumulating leakage in a separate chamber prior to the transfer to the NMR analysis system (Figure 1, #34; Column 4, lines 47-67).

10. With respect to claim 49, Davey discloses the step where the accumulation of material for analysis also occurs within the NMR analysis system (Column 4, lines 64-67).

Art Unit: 2859

11. With respect to claim 51, Davey discloses the method with any of the steps of: moving the accumulation chamber into an NMR analysis system; transferring the accumulation chamber contents into a second container for analysis and then transferring the second container contents into an NMR analysis system; and transferring the accumulation chamber contents into a second container for analysis and then moving this container for analysis into an NMR analysis system (Columns 4 and 5, lines 47-67 and 1-6 respectively).

12. With respect to claim 53, Davey discloses the method with any of the steps of: cooling the materials; accumulating leakage on a cooled surface then measuring the amount accumulated; accumulating the leakage on a cooled surface located within the NMR analysis system, to accumulate materials directly within the NMR analysis system, and accumulating the leakage on a cooled surface and moving the cooled surface relative to an NMR analysis system, to carry out the measurement after a period of accumulation (Columns 4 and 5, lines 47-67 and 1-6 respectively).

13. With respect to claim 54, Davey discloses the step of evacuating the chamber that is to be used for accumulation prior to transfer into the NMR analysis system before accumulating material leakage (Columns 4 and 5, lines 47-67 and 1-6 respectively).

14. With respect to claim 55, Davey discloses a test equipment having means for validating inhaler integrity using a NMR analysis system for analysis of material leakage accumulated within the NMR analysis system (Abstract; Columns 4 and 5, lines 35-67 and 1-6 respectively).

15. With respect to claim 56, Davey discloses the test equipment having any of: a transfer type vacuum pumping system means for transferring material leakage into the NMR analysis

Art Unit: 2859

system, a pressure pumping system means for transferring material leakage into the NMR analysis system, and a transfer type vacuum and pressure pumping system combination for transferring material leakage into the NMR analysis system (Figure 1, vacuum pump system #26).

16. With respect to claim 57, Davey discloses the test equipment being arranged to transfer the accumulated material to another chamber means for introduction into the NMR analysis system for analysis of the leakage (Column 4, lines 47-67; Figure 1, from chamber #20 to #34 and to MR chamber #44).

17. With respect to claim 60, Davey discloses the test equipment being arranged to pre evacuate the accumulation chamber (Column 4, lines 47-67; Figure 1, from chamber #20 to #34 and to MR chamber #44).

18. With respect to claim 63, Davey discloses the test equipment having apparatus arranged to cross check integrity validation with an off-line NMR analysis system (Column 4, lines 47-67; Figure 1, #16).

19. With respect to claim 64, Davey discloses a product validated by the method of claim 42 (Abstract; Column 4, lines 47-67; Figure 1, #16).

***Allowable Subject Matter***

20. Claims 45, 50, 52, 58, 59 and 61-62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 2859

21. The following is a statement of reasons for the indication of allowable subject matter:

a. With respect to claim 45, the claim has been found allowable over the prior art of record because the prior art of record fails to teach or fairly suggests a method of testing integrity of a barrier comprising the step of using a sniffing probe means that can be moved relative to the surface of the barrier so as to allow materials to be collected from different positions relative to the barrier for transfer into the NMR analysis system in combination with the remaining limitations of claim 40 above.

b. With respect to claim 50, the claim has been found allowable over the prior art of record because the prior art of record fails to teach or fairly suggests a method of testing integrity of a barrier comprising the step where some or all of the fluid material contains fluorine compounds, and the NMR analysis involves detecting fluorine in combination with the remaining limitations of claim 40 above.

c. With respect to claim 52, the claim has been found allowable over the prior art of record because the prior art of record fails to teach or fairly suggests a method of testing integrity of a barrier comprising the step of carrying out the NMR analysis for multiple barriers, multiple containers, or both types, simultaneously in combination with the remaining limitations of claim 40 above.

d. With respect to claim 58, the claim has been found allowable over the prior art of record because the prior art of record fails to teach or fairly suggests a test equipment where the fluid is fluorine containing and the NMR analysis is for  $^{19}\text{F}$  nuclei contained within the fluid molecules in combination with the remaining limitations of claim 55 above.

Art Unit: 2859

e. With respect to claim 59, the claim has been found allowable over the prior art of record because the prior art of record fails to teach or fairly suggests a test equipment comprising a cooled surface and apparatus for transferring material accumulated on the cooled surface to the NMR analysis system in combination with the remaining limitations of claim 55 above.

f. With respect to claim 61, the claim has been found allowable due to its dependency on claim 59 above.

g. With respect to claim 62, the claim has been found allowable over the prior art of record because the prior art of record fails to teach or fairly suggests a test equipment having a calibrator arranged to use a material of the chamber to provide a calibration means for the NMR analysis system in combination with the remaining limitations of claim 55 above.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dixomara Vargas whose telephone number is (571) 272-2252.

The examiner can normally be reached on Monday to Thursday from 8:00 am. to 4:30 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diego Gutierrez can be reached on (571) 272-2245. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 2859

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Dixomara Vargas  
Patent Examiner  
Art Unit 2859